

**R E M A R K S**

Claims 1-12 are currently pending in the present application. Claims 13 and 14 have been cancelled herein. As a preliminary matter, Applicants wish to affirm that the Examiner's presumption that the subject matter of the various claims was commonly owned at the time the present invention were made is correct.

Further consideration on the merits is respectfully requested.

***Rejections under 35 U.S.C. §112, Second Paragraph – Indefiniteness***

Claims 13 and 14 stand rejected under 35 U.S.C. §101 and 35 U.S.C. §112 for including improper "use" language. Claims 13 and 14 have been cancelled herein, thereby rendering the outstanding rejection moot. Withdrawal thereof is respectfully requested.

***Rejections under 35 U.S.C. §102 – Anticipation***

Claims 1-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by USP 5,116,868 to Chen et al. (hereinafter "Chen").

Claims 1-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by USP 6,495,598 to Yoneda et al. (hereinafter "Yoneda").

Claims 1-14 stand rejected under 35 U.S.C. §102(b) or 35 U.S.C. §102(a) as being anticipated by JP 2003-313123 to Tomoko et al. (hereinafter "Tomoko").

Applicants respectfully traverse each of the outstanding rejections. Each of the cited prior art references will be addressed in turn.

Chen

The Examiner states the following regarding Chen:

Their teachings also clearly indicate that this irrigation composition is also particular importance to the cornea, and cornea obtains its nourishment from tear. Thus this composition has important role in maintenance of tear function (Col. 1, lines 34-38)

Although Chen teaches that the disclosed irrigating composition has an important effect on the cornea, the experiments performed by Chen on the corneal endothelium protecting effect of the irrigating composition containing D-β-hydroxybutyric acid during use in ophthalmic operation is merely limited to this efficacy.

The corneal endothelium obtains its nourishment from an aqueous fluid in the eye and not from tear. Therefore, even when the irrigating composition containing D-β-hydroxybutyric acid has a corneal endothelium protecting effect, it cannot be said that this irrigating composition has an important role in the treatment of the tear function. Thus, Chen merely discloses a composition which suppresses a corneal endothelial lesion in ophthalmic operation and not a composition for the treatment of a corneal lesion or tear function.

Therefore, the Chen disclosure is completely different from the present invention, and one of ordinary skill in the art would not arrive at the present invention from consideration of the Chen disclosure. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

Yoneda

The Examiner states the following regarding Yoneda (page 3, line 3 from the bottom to page 4, line 3 of the outstanding Office Action):

Their teachings indicate that their irrigating solution is suitable for protecting intraocular tissues, and also prevents the surface of the corneal epithelium and the conjunctiva from drying in order to perform the surgery safely and effectively

(Col. 1, lines 10-15). Thus they clearly indicate use of their irrigating ophthalmic composition containing D-3-hydroxybutyric acid is useful for treating keratoconjunctiva which is a disease of conjunctiva and drying that results due to tear dysfunction.

The Yoneda inventors conducted experiments on the efficacy of an irrigating ophthalmic composition containing D-3-hydroxybutyric acid and its effect of protecting the corneal endothelium when this composition is used in an eye operation (i.e., cataract operation) and merely proved its efficacy. In general, the surface of the eye is kept wet by blinking.

However, since ophthalmic operation (i.e., cataract operation) is carried out while the eye is opened, the eye surface is dry. An irrigating solution is used to prevent eye dryness during the operation. Thus, the purpose of the disclosed irrigating solution is limited to preventing the eye from drying during the operation. Those of ordinary skill in the art would appreciate that keratoconjunctivitis caused by drying of the eye surface due to tear dysfunction or abnormal secretion (i.e., dry eye) is completely different from a lesion on the surface of the eye caused by drying during the ophthalmic operation. Therefore, the Examiner's assertion that use of the irrigating ophthalmic composition containing D-3-hydroxybutyric acid is useful for the treatment of a conjunctival disease or keratoconjunctivitis such as drying caused by tear dysfunction is improper.

Accordingly, the Yoneda disclosure is completely different from the present invention, and one of ordinary skill in the art would not arrive at the present invention from consideration of the Yoneda disclosure. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

*Tomoko*

The Examiner states the following regarding Tomoko (page 4, lines 5-8 from the bottom of the outstanding Office Action):

Tomoko et al teach a composition for preventing and or treating ophthalmopathy caused by apoptosis. Their teachings include use of 3-hydroxybutyric acid and/or its salt as an active ingredient for treating keratoconjunctivitis (Abstract).

Applicants acknowledge that Tomoko discloses a composition for preventing and/or treating ophthalmopathy caused by apoptosis, which contains 3-hydroxybutyric acid and/or a salt thereof. However, Tomoko does not teach that the ophthalmopathy caused by apoptosis includes eye disease caused by drying (see claim 1).

"Dry eye" is defined as a corneal epithelial lesion caused by the qualitative or quantitative abnormality of tear in a narrow sense and includes the abnormality of tear which is not accompanied by a corneal epithelium lesion. Tomoko discloses a composition for preventing and/or treating ophthalmopathy caused by apoptosis excluding "dry eye".

However, the present Applicants invented a composition for treating "dry eye" by restoring the fine structure of a corneal epithelium cell to its normal state. Therefore, the Tomoko disclosure is completely different from the present invention, and one of ordinary skill in the art would not arrive at the present invention from the Tomoko disclosure. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

#### ***Rejection under 35 U.S.C. §103 – Obviousness***

Claim 12 stands rejected under 35 U.S.C. § 103 as being unpatentable over Chen or Tomoko. Applicants respectfully traverse.

Chen discloses a composition containing D-3-hydroxybutyric acid which suppresses a corneal endothelial lesion in ophthalmic operation, and Tomoko discloses a composition containing 3-hydroxybutyric acid and/or a salt thereof, for preventing and/or treating ophthalmopathy caused by apoptosis excluding ophthalmopathy caused by "dry eye". See the discussions of Chen and Tomoko above.

However, in contrast to Chen and Tomoko, the present Applicants have surprisingly found that D-3-hydroxybutyric acid has the function of restoring the fine structure of a corneal epithelium cell to its normal state unlike the disclosures of Chen and Tomoko.

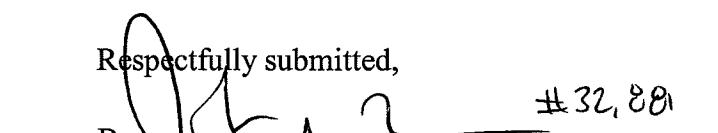
Therefore the present invention, as recited in claim 12, would not have been obvious in light of the disclosures of Chen and Tomoko.

In view of the foregoing, Applicants believe the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,  
  
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